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EXAMINER	
HINES, JANA A	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/982,992	PATTI ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12,14-21 and 23-32* is/are pending in the application.

4a) Of the above claim(s) *15-17,19-21 and 27-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-12, 14, 18, 23-26 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2005 has been entered.

Amendment Entry

2. The amendment filed October 21, 2005 has been entered. Claims 1 and 6-8 have been amended. Claims 5, 13 and 22 have been cancelled. Claims 1-4, 6-12, 14, 18, 23-26 and 30-32 are under consideration in this office action.

Withdrawal of Rejections

3. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The objection of claim 8 under 37 CFR 1.75(c);

b) The rejection of claims 1-4, 13-14 and 24 under 35 U.S.C. 102(b) as being anticipated by Hook et al., (US Patent 5,648,240); and

c) The rejection of claims 5-8 under 35 U.S.C. 103(a) as being obvious over Hook et al., (US Patent 5,648,240) further in view of Hook (US Patent 6,288,214).

Response to Arguments

4. Applicant's arguments filed October 21, 2005 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

5. The use of the trademarks such as QIAGEN™, SIGMA™, SEPHAROSE™ on pages 9,10 and 28 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

6. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, is maintained for reasons already of record. It is unclear how the monoclonal antibody of claim 1 comprises an antibody fragment. Moreover, it is unclear how this antibody fragment will recognize the same epitopes recognized by an antibody which binds to the full length *S. aureus* MAP protein, if as applicants urge, such antibodies are not directed to the specific MAP10 region. Thus, the metes and bounds of the term cannot be ascertained since there is no standard for determining the same epitopes, or antibody recognition abilities. Therefore, clarification is required to overcome the rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-3, 8 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc.,107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court

determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, claims 2-3 and 18 are drawn to antibodies wherein said antibody prevents *S. aureus* infection in a human or animal and wherein the antibody inhibits binding of staphylococcal bacteria to eurkaryotic cells. The written description in this case only sets forth monoclonal antibody isotype H07 MAP.10 Mab IgG_1 and all anti-Map10 antibodies are capable preventing *S. aureus* infection or inhibiting binding of staphylococcal bacteria to eurkaryotic cells. The specification at page 29 clearly states that monoclonal antibody isotype H01 MAP.10 Mab IgG_1, had no efficacy. However the claims encompass all types of antibodies which bind to the Map10 protein, including antibodies undiscovered and/or unknown to have said binding ability. The written description in this case only sets forth the specific antibodies listed on page 27 of the instant specification and all the antibodies do not have all the claimed characteristics. The specification fails to provide ample written description for the antibodies since the claims do not describe a singe structural feature.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claims 2-3 are broad generic claims with respect all possible antibodies encompassed by the claims. The possible structural variations are limitless. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient as a characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between

function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lacks a sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is limited to the above mentioned antibodies. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Claim 8 is drawn to an antibody fragment which recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP protein. The written description in this case fails to sets forth an antibody fragment which recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP protein. There is no description of what these same epitopes are or the identity of the antibody which binds to the *S. aureus* MAP protein. The claims encompass all types of antibodies which bind to the Map protein, including antibodies undiscovered and/or unknown to have said binding ability. There is no epitope map by which to compare the antibody fragment and the antibody which binds the MAP protein. The specification fails to provide ample written description for the antibody fragments or the anti-MAP antibodies since the claims do not describe a singe structural feature. Furthermore, the specification lacks a sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives.

The skilled artisan cannot envision the detailed structure of the encompassed antibodies and therefore conception is not achieved until reduction to practice has

occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. The claims drawn to antibody fragment contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention i.e., antibody fragments that recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP protein. Thus applicants' has not demonstrated possession of the generic inventions encompassed by these claims. There is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645; therefor the claims are rejected.

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Deposit Rejection

8. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a deposit rejection

The specification lacks complete deposit information for the deposit of hybridoma producing mAb H07. Because it is not clear that cell lines possessing the properties of mAb H07 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of mAb H07, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

If a deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposit has not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridoma cell line described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §1.801-1.809 for further information concerning deposit practice.

Enablement Rejection

9. Claims 2-3 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The genus encompasses antibodies wherein said antibody prevents *S. aureus* infection in a human or animal and wherein the antibody inhibits binding of staphylococcal bacteria to eurkaryotic cells, however the antibodies have numerous differences in amino acid sequences, including numerous differences in linear and conformational epitopes.

However, the specification does not provide enabling disclosure that evidences the antibodies listed on page 27 facilitate activities presented in the claims, for instance as being capable of preventing *S. aureus* infection and inhibiting binding of staphylococcal bacteria to eurkaryotic cells. The specification teaches that monoclonal H01 had no efficacy in the mouse bacteremia mouse models (page 29 para. [0060]). Moreover, the specification does not provide sufficient guidance as to which of the amino acids may be changed and still maintain the structural or functional activity and specificity required by the claims. It is noted that applicants teaching regarding specific Map10 antibodies is limited, yet the scope of the claims is quite broad. The claims read on any antibody that binds Map10 protein, including undiscovered antibodies or antibodies that are not currently known to have said binding ability. For example, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). For example, Li et al. (PNAS 77: 3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Because of this lack of guidance, the extended experimentation that would be required to determine which modifications would be acceptable to retain occluding structural and functional activity, and the fact that the relationship between the sequence of a protein/peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo et al.; in The Protein Folding Problem and Tertiary Structure Prediction,1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp.

433 and 492-495.), it would require an undue amount of experimentation for one of skill in the art to arrive at the other Map10 antibodies encompassed by the claimed invention.

The scope of the claimed Map10 specific antibodies is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of Map10 proteins and antibodies broadly encompassed by the claimed invention. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's or peptide's amino acid sequence, and, in turn, nucleic acid sequence, and still retain similar biological activity or structural specificity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, the problem of predicting protein structure from mere sequence data of a limited number of proteins/nucleic acids and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and finally what changes can be tolerated with respect thereto is extremely complex and well outside the realm of routine experimentation.

Thus, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use of the claimed Map10 antibodies in a manner reasonably correlated with the scope of the claims broadly including a broad number of structural changes encompassed by amino acid substitution variants of the Map10 protein. The

scope of the claims must bear a reasonable correlation with the scope of enablement. See *In re Fisher*, 166 USPQ 19 24 (CCPA 1970). Without such guidance, the changes which can be made are unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

New Matter Rejection

10. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for an antibody fragment which recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP protein. Applicant did not point to support in the specification for an antibody fragment which recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP protein. Moreover, applicant failed to specifically point to the identity or provide structural characteristics of the antibody fragment that recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP protein. Thus, there appears to be no teaching of an antibody fragment which recognizes the same epitopes recognized by an antibody which binds to the *S. aureus* MAP protein. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number support for the identity an antibody fragment which recognizes the same epitopes

recognized by an antibody which binds to the *S. aureus* MAP protein as recited by the newly amended claim. Therefore, the claim incorporates new matter and is accordingly rejected.

11. Dependant claims 2-4, 6-12, 23, and 30 refer to "an antibody", however the suggested claim language is to use of the article "the." Therefore the suggested claim language is "the antibody".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1-4, 6-12, 18, 23-24, and are rejected under 35 U.S.C. 101 because a monoclonal antibody that binds to the Map10 protein from *S.aureus* as described by the claims is a product of nature. Antisera containing antibodies can be produced from the *S. aureus* bacteria. The claims do not require that the antibody be isolated. Insertion of the terms "isolated or purified" would obviate this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-4, 6-12, 14, 18, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hook et al., (US Patent 5,648,240) in view of Kohler and Milstein (Nature, 1975. Vol. 256:495-497). The claims are drawn to a monoclonal antibody that binds to the Map10 protein from *Staphylococcus aureus*. The dependant claims are drawn to the antibody treating or preventing infection; being suitable for administration, specific types of monoclonal antibodies; and antisera.

Hook et al., teach the MHC II-antigen protein analog gene from *Staphylococcus aureus* (col. 2 lines 35-37). The gene and protein of the instant application designated as Map10, is the same gene and protein as recited by the instant claims. See the instant specification at page 5. The strains of both the instant application and Hook et al., used were *S. aureus* FDA 574. Example 6 teaches the use of Western blotting techniques to detect the antigen. It is well known in the art that the Western immunoblot is a method that identifies antibodies against proteins of a precise molecular weight wherein the antigen is exposed using a radioisotope-labeled antibody. Thus, the antibodies bind to the MAP 10 protein. Example 9 teaches the testing of antibodies for the inhibitory capacity of the binding of *S. aureus*. Hook et al., (5,648,240) has been previously discussed. However Hook et al., do not recite a monoclonal antibody which is a single chain antibody or selected from the group consisting of chimeric, humanized or human monoclonal antibodies or an antibody fragment that has the same binding specificity of an antibody which binds to the MAP protein.

Kohler and Milstein teach the production of monoclonal antibodies. Furthermore, they teach the preparation of chimeric, humanized, or human monoclonal antibodies in

ways that are well known in the art. Further still, they teach preparing single chain monoclonal antibodies and active fragments which retain the binding characteristics of the whole antibody.

Therefore, it would have been prima facie obvious at the time of applicants invention to modify the antibodies of Hook et al., ('240) to prepare or characterize the antibodies as monoclonal single chain antibody, humanized antibodies or fragments that have the same binding specificity as taught by Hook et al., ('240) since such techniques are well known in the art. No more than routine skill would have been required to generate any of these antibodies or antibody fragments since such techniques are well known in the art. Moreover, one would have had a reasonable expectation of success in preparing or characterizing the claimed antibodies since such antibodies will bind to the minimal binding region found in Map10 which also binds the whole MAP protein.

Conclusion

14. No claims allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
January 9, 2006

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